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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,741	01/30/2004	Ryan C. Lakin	5490-000250/CPB	6558

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EXAMINER	
STOKES, CANDICE CAPRI	
ART UNIT	**PAPER NUMBER**
3732	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/769,741	LAKIN ET AL.	
	Examiner	Art Unit	
	Candice C. Stokes	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *33* is/are allowed.

6)☒ Claim(s) *1-32,34-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1) Claims 1-21, and 38-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al (USPN 5,989,293) in view of Sullivan et al (US 2003/0125810). Cook et al disclose an acetabular prosthetic comprising: a bone engagement surface (outer portion of 14); a first inner integral generally spherical concave bearing surface 28; and a locking mechanism 29 configured to couple a second prosthetic implant 16 (see column 3, lines 2-6) having a second spherical bearing surface 39, the second spherical concave bearing surface 39 is configured to substantially surround a head of a femoral component (see column 3, lines 62-64). As to claims 2 and 9, the second prosthetic is selected from a group of a constraining ring, a slotted constraining ring, a bearing insert, and a bearing insert having an integral constraining ring and combinations thereof. Regarding claim 3, the first inner integral generally spherical concave bearing surface 28 is a polished metal (see column 3,line 10). As to claim 4, the acetabular prosthetic further comprises a peripheral surface 30, which defines said locking mechanism 34, and wherein said peripheral surface 30 defines at least one aperture (where reference 34 abuts) configured to accept a coupling fastener. With respect to claim 5, the second prosthetic implant 16 may be substituted with plastic ring 18. Inherently, plastic is a polymer bear surface. With regards to claims 6-7 and 9, the second prosthetic 16 is a bearing insert and also an integral

constraining ring. As to claims 8 and 11, the bearing insert defines a bearing insert coupling groove 47 configured to accept a locking ring 34. Figure 2 shows that the constraining ring includes a hemi-spherical bearing surface. This anticipates claim 10. As to claim 11, said constraining ring defines a constraining ring groove 47 configured to accept a locking ring 34 to couple said constraining ring to said first prosthetic 14. Regarding claims 12 and 41, said constraining ring defines a locking flange 47, said locking flange 47 being configured to mate with said locking mechanism 29. As to claims 13 and 17, said constraining ring comprises a metal reinforcement ring 39. Cook et al also disclose said constraining ring comprising a restraining lip (where reference 39 is shown). This anticipates claim 14. Further to claim 15, the constraining ring 16 comprises a plurality of restraining lips (see Figure 2 which shows another lip below where reference 39 is shown). With regards to claim 16 and further regards to claim 41, the constraining ring 16 comprises an exterior surface which defines a reinforcement accepting groove 47, said reinforcement accepting groove 47 being configured to retain a reinforcement ring (30 of prosthetic 14). As to claims 17 and 38, the constraining ring 16 comprises an integrally molded reinforcement structure 39. Further to claims 19 and 40 the reinforcement structure 39 is a bearing insert. With regards to claims 20 and 42, the constraining ring comprises a coupling plate 38 having a plurality of elastically deformable coupling flanges 36 which are capable of coupling to the locking mechanism. Also to claim 21, the first and second bearing surfaces define a generally capsule shaped cavity (as best shown in Figure 6) capable of rotatably accepting a head of a femoral prosthetic and allowing translation of the head along a predetermined axis. With further respect to claim 41, the locking mechanism defines a flange member, which is capable of being positioned beneath a locking tab defined by an

acetabular cup. As to claim 43, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Thus, the limitation of the constraining ring being "configured to be rotatable..." is met by the Cook et al reference. Cook et al substantially discloses the claimed invention as amended except, they do not claim the concave bearing surface being polished. Sullivan et al teach "the bearing surface of the prosthesis which should have minimum friction and maximum resistance to wear can be formed of a very hard material such as a high density ceramic or a CoCrMo alloy or other hard bio compatible material, polished to a smooth bearing surface. It would have been obvious to one having ordinary skill in the art to incorporate a polished bearing surface such as that taught by Sullivan et al into the prosthetic disclosed by Cook et al in order to minimize the friction and maximize the wear resistance of the bearing surface. Further to the amended version of claims 1,22,27, and 34 the term "configured to directly engaged..." is also met by this rejection because the bearing surface as disclosed is capable of directly engaging an articulating surface.

Claims 18 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. Cook et al disclose the claimed invention except for the reinforcement structure of the constraining ring having a c-shaped cross-section. It would have been an obvious matter of design choice to make the ring having a c-shaped cross-section, since such a modification would have involved a mere change in the shape of a component. A change in shape is generally recognized as being within the level of ordinary skill in the art.

2) Claims 1-17,19-32, and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray, III (USPN 5,800,555) in view of Sullivan et al (US 2003/0125810). As to claim 22, Gray discloses a kit of prosthetic components 10 comprising: an acetabular prosthetic 12 defining an integral spherical bearing surface 38 and a locking mechanism 16 configured to accept a second prosthetic device 14; at least one second prosthetic device 14 having a partially spherical bearing surface 72, the partially spherical bearing surface 72 is configured substantially surround a head 78 of a femoral component 80; and a femoral prosthetic 80. Regarding claim 23, said second prosthetic device 14 is selected from a group consisting of a constraining ring, a bearing insert, a bearing having an integral constraining ring, and combinations thereof. As to claim 25, said second prosthetic device 14 is a constraining ring defining a constraining ring bearing surface 72 and a constraining ring locking mechanism 16 configured to fixably couple said constraining ring to said acetabular prosthetic 12. With regards to claims 26 and 29-31, the second prosthetic device 14 is a polymer bearing insert (see column 4, lines 15-16) which defines an interior bearing surface 72 and a bearing insert locking mechanism 16, wherein said bearing insert locking mechanism 16 is configured to lock said polymer bearing insert to said acetabular prosthetic 12. As to claim 27, Gray also discloses a method for implanting a medical device comprising: implanting a first prosthetic 12 having an integral internal bearing surface 38 and a locking mechanism 16 which is configured to fixably accept a second prosthetic 14 having a second bearing surface 72 which substantially surrounds a head portion 78 of a femoral component 80, to a prepared joint; and inserting a femoral prosthetic 80 within the integral internal bearing surface 38 of the first prosthetic 12. As to claim 28, the method further comprising coupling a device second prosthetic device 14 to the locking

mechanism 16 after the first prosthetic device 12 has been implanted in the prepared joint. Regarding claim 32, the method further comprising: removing the femoral prosthesis 80 from said first prosthetic 12, coupling said second prosthetic 14 to said first prosthetic 12, and inserting the femoral prosthesis 80 into said first and second prosthetics 12,14. As to claims 34-36, Gray also discloses, an acetabular prosthetic implant comprising: a first member having a bone engagement surface and an integral generally spherical first bearing surface, said first member defining a locking mechanism configured to be coupled to a second prosthetic member; and a second prosthetic member, coupled to said locking mechanism, said second member defining a second semi-spherical bearing surface (see column 3, line 35), said first and second bearing surfaces defining a generally capsule shaped cavity, and wherein said generally capsule shaped cavity is configured to rotatably accept a head of a femoral prosthetic and allow the translation of the head along a predetermined axis. Gray, III et al substantially discloses the claimed invention as amended except, they do not claim the concave bearing surface being polished. Sullivan et al teach "the bearing surface of the prosthesis which should have minimum friction and maximum resistance to wear can be formed of a very hard material such as a high density ceramic or a CoCrMo alloy or other hard bio compatible material, polished to a smooth bearing surface. It would have been obvious to one having ordinary skill in the art to incorporate a polished bearing surface such as that taught by Sullivan et al into the prosthetic disclosed by Gray, III et al in order to minimize the friction and maximize the wear resistance of the bearing surface. Further to the amended version of claims 1,22,27, and 34 the term "configured to directly engaged..." is also met by this rejection because the bearing surface as disclosed is capable of directly engaging an articulating surface.

Regarding claim 24 Gray discloses the claimed invention except for the kit comprising a plurality of femoral prosthetic components. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include more than one femoral component within the kit, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

As to claim 37, Gray discloses the claimed invention except for the generally cylindrical bearing surface having a length of about 1 to about 4mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the bearing surface any desired length suitable for its intended use, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Allowable Subject Matter

Claim 33 is allowed.

Response to Arguments

Applicant's arguments with respect to claims 1,22,27, and 34 have been considered but are moot in view of the new ground(s) of rejection.

Regarding claim 38, "Applicant's note that the reinforcement ring of the '293 reference is not reinforced, let alone with an integrally molded reinforcement ring" (see page 14, bottom). It is the position of the Office that the reinforcement ring is not claimed as being reinforced whether integrally molded or otherwise. Further the Office submits that ring 39 in the '293 patent reinforces the constraining ring 16 and is formed integrally therewith.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Candice C. Stokes whose telephone number is (571) 272-4714. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Candice C. Stokes

CRIS L. RODRIGUEZ
PRIMARY EXAMINER